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SMART MEDICAL CONNECTOR SYSTEM AND METHOD OF USE

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SMART MEDICAL CONNECTOR SYSTEM AND METHOD OF USE

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

This invention relates generally to a method and apparatus for identifying electrodes attached to a defibrillator. In particular, this invention relates to providing an identification module within the electrode connector. The electrotherapy device identifies the electrodes attached to the patient based on the identification module and adjusts defibrillator operation based upon the identification. Electrotherapy devices include defibrillators, cardioverters and training devices that simulate the operation of an electrotherapy device. Defibrillators include automatic or semi-automatic external defibrillators (AEDs).

DESCRIPTION OF THE PRIOR ART

Electrotherapy devices are used to provide electric shocks to treat patients for a variety of heart arrhythmias. For example, external defibrillators typically provide relatively high-energy shocks to a patient (as compared to implantable defibrillators), usually through electrodes attached to the patient's torso. External defibrillators are used to convert ventricular fibrillation or shockable tachycardia to a normal sinus rhythm. Similarly, external cardioverters can be used to provide paced shocks to convert atrial fibrillation to a more normal heart rhythm.

In 1991 the Advanced Cardiac Life Support Subcommittee of the American Heart Associate made a report to Health Professionals calling for increased access to defibrillation in order to improve the survival rates from sudden cardiac arrest (SCA). [Cummins, et al. "Improving Survival From Sudden Cardiac Arrest: The 'Chain of Survival' Concept" Circulation **83(5):** 1832-1847 (1991).] The statistics themselves are staggering. On average 1000 adults die from SCA each day. Over 70% of these deaths occur in the home. Because the survival rate decreases 10% for every minute that passes, unless a defibrillator is available within the first few critical minutes, a victim of

SCA has little chance of survival. If defibrillation were available, many of these people would survive. Following the AHA's recommendations, there has been increased awareness of the importance of public access defibrillation and defibrillators have become increasingly available. [*See, e.g.,* Newman, "Early Defibrillation – Making Waves Across America," JEMS Suppl. S4-S8 (January 1997).] The first phase of early defibrillation has been training designated lay responders in proper deployment of a defibrillator. Designated lay responders include, for example, fire fighters, police officers, flight attendants and security guards. However, with 70% of SCA occurring in the home, it becomes increasingly important to design a device that can be deployed by the average citizen in a home emergency.

One problem that could arise as defibrillators become ubiquitous relates to the ability to modify defibrillator operation based on the patient, *e.g.* infant, pediatric or adult. Currently, AEDs operate according to a single protocol for all patients and are generally not configured for use on children under 8 (the definition of pediatric patients according to the American Heart Association). As more information becomes available about the incidence of SCA in pediatric patients, it will likely be important to provide a mechanism to defibrillator a pediatric patient that is uncomplicated.

What is needed is a method and apparatus for identifying the electrodes to the defibrillator.

SUMMARY OF THE INVENTION

An electrical medical electrode connector is provided. The electrical medical electrode connector comprises: a housing, wherein at least one end of the housing forms a cable connector; an electrical conductor electrically connected to a socket within a shell of the cable connector; and an identifier disposed within the housing that communicates information to a defibrillator. A pair of defibrillator electrodes may be electrically connected to the housing. Alternatively, a set of monitoring pads electrically connected to the housing. In either case, the medical electrode is typically comprised of a plurality of electrode pads. For the monitoring scenario, a preferred embodiment

incorporates three electrode pads, five electrode pads or twelve electrode pads. The identifier communicates an identification value from the medical electrode. The communication values can be those corresponding to: light amplitude, wavelength, polarization, hertz, resistance, capacitance, gauss, electrical contact. The identifier may be optical, electromechanical, electrical, resistive, capacitive, or magnetic.

A defibrillator system is also provided. The defibrillator system comprises: at least one electrode pad having an electrode pad type operable to contact a patient; a medical electrode connector, connected to the defibrillator electrode pad on one end and the defibrillator on the other end, operable to identify the electrode pad type to the defibrillator; a front-end circuit operation to be coupled to the electrode pad and to receive identification information from the electrode pad; a shock delivery circuit coupled to the electrode pad; and a processor coupled to the front-end and shock delivery circuits and operable to determine whether the patient is experiencing a shockable heart condition and to enable the shock-delivery circuit to deliver a shock to the patient via the electrode pads if the processor determines that the patient is experiencing a shockable heart condition. The medical electrode connector is removably connectable to the defibrillator. The defibrillator of claim 10 wherein the medical electrode connector is removably connectable to the electrode pads. The medical electrode connector has an identification module operation identify the electrode pad type to the defibrillator. The identification module communications at least one identification value to the defibrillator. The identification value can be any of light, open/short, resonant frequency, resistance, capacitance, or gauss. An identifier receiver operable to interface between the medical electrode connector and the front-end circuit may also be provided.

A method of deploying a defibrillator is also contemplated. The method comprises: turning the defibrillator on; attaching electrode pads to a patient; inserting a cable connector associated with the electrode pads into a housing for receiving the cable connector within the defibrillator; identifying the type of electrode pads based on

an identifier within the cable connector associated with the electrode pads; altering therapy delivered by the defibrillator based on the type of electrode pads identified; and altering patient care instructions such as CPR based on the type of electrode pads identified. Additionally, the amount of energy delivered to a patient in response to the electrode pad identification may be adjusted. Applicant also contemplates lowering the amount of energy delivered to a patient if the electrodes are identified as infant electrodes or child electrodes. Otherwise, the defibrillator will follow a default therapy protocol if the electrode identification value is not recognized or if no electrode identification value is received. A patient treatment protocol, such as CPR, may also be altered to conform to the type of patient being treated in response to the identification. In that case, the protocol would be changed to the infant CPR protocol if the electrodes are identified as infant electrodes, child CPR protocol if the electrodes are identified as child electrodes, a default CPR protocol if the electrode identification value is not recognized or if no electrode identification value is received. The CPR protocol may be the CPR protocol recommended by the American Heart Association if the electrodes are identified as AHA electrodes or the CPR protocol recommended by the European Resuscitation Council if the electrodes are identified as ERC electrodes. Thus, the method includes indicating use of the CPR protocol recommended by specific organizations if the electrodes are identified as electrodes specific to that organization.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of an electrotherapy device showing a detachable electrode system. In **FIG. 1**, the electrode system ***36*** includes an identification module or identifier ***32***, an electrode adapter ***26*** and electrodes ***28***.

FIG. 2a is a perspective drawing of an electrode system comprising a pair of disposable electrodes integrally formed with an electrode connector that includes features that identify the type of disposable electrodes attached to the connector. **FIG. 2b** is a perspective drawing of an electrode connector receptacle in the form of an adapter having an identification module for use in connection with a defibrillator and a pair of disposable electrodes. **FIG. 2c** is a perspective drawing of an electrode

connector receptacle in the form of an adapter having an identification module for use in connection with a defibrillator and a pair of disposable electrodes showing the interior portions of the male and female ends of the adapter.

FIG. 3 shows the major components of a semi-automatic external defibrillator in block diagram form.

FIG. 4 is a flow chart showing the method of operating the electrotherapy device according to the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following discussion is presented to enable a person skilled in the art to make and use the invention. Various modifications to the preferred embodiment will be readily apparent to those skilled in the art, and the generic principles herein may be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiment show, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

FIG. 1 is a block diagram showing a device ***10***. Device ***10*** is an electrotherapy device. The device ***10*** may include the ability to defibrillate, cardiovert, or pace a patient, or a combination of these features. Device ***10*** has a controller ***12*** that operates an energy delivery system ***14*** and performs other aspects of the operation of the device. Software instructions for the operation of the device are accessible from read only memory (ROM), such as incorporated ROM ***16***. The controller accesses instructions for operation from ROM ***16***. It should be understood that, in this and other embodiments described below, "controller" means a microprocessor, controller, gate array, other control logic, or any combination of these elements. The device components are typically located within a device housing ***40***. The device housing ***40*** has receptacle ***42*** for receiving an electrode connector ***26***.

As contemplated by this embodiment, an identification module ***32*** is integral with the electrode connector ***26***. The electrode connector ***26*** is connected to electrodes ***28,***

the whole assembly being removably connected to the receptacle ***42*** in device housing ***40***. The identification module ***32*** in the adapter ***26*** uniquely identifies the electrode connector ***26*** to the defibrillator. Thus, identifying the type of electrodes attached to the defibrillator. A suitable electrode system ***36*** to be adapted for use in this invention would be, for example, Heartstream ForeRunner® electrodes.

Once the electrode connector ***26*** is attached to the device ***10***, identification module ***32*** communicates with controller ***12***. Communication with the controller ***12*** may be direct or through an identifier receiver (not shown) which interfaces between the controller ***12*** and the identifier ***32***.

Electrodes ***28*** communicate with a patient monitor ***24*** via the electrode connector ***26*** attached to the device ***10*** through receptacle ***42.*** Electrodes ***28*** provide patient ECG data from the patient to the patient monitor ***24***. Electrodes include electrodes capable of delivering defibrillation, monitoring a patient condition, delivering pacing pulses, or a combination of those features. In an AED, the patient monitor ***24*** monitors the patient for a heart rhythm and subsequently determines whether the monitored rhythm is shockable. When the rhythm is shockable, the patient monitor ***24*** then communicates a shock decision to the controller ***12***. The controller ***12***, then communicates to the energy delivery system ***14***. The energy delivery system ***14***, then delivers a therapeutic energy pulse to the patient (not shown) through electrodes ***28*** attached to the defibrillator ***10*** via electrode connector ***26***, using the power supply ***20*** as the energy source. As will be appreciated by those of skill in the art, the identification module ***32*** may be any of a number of solutions, discussed in more detail below.

In one embodiment, an optical encoding solution is contemplated. In this scenario, a light source is provided in view of a photosensitive light receiver in the body of the defibrillator near to or part of the electrode connector ***26***. Integrated into the electrode connector ***26*** are devices that will alter the characteristics of the light as received by the photosensor. In a simple embodiment the characteristic would be detection of the presence or absence of one or more windows in the connector body by detecting the presence or absence of light impinging upon the photosensor. In this

case, the light source and photosensor would be arranged such that they straddle the electrode connector receptacle. As one skilled in the art can appreciate, a plurality of windows would permit encoding of the type of electrode attached to the connector. A more sophisticated approach would use a window or windows of varying optical density or color which would vary the amplitude or wavelength of the received light. The use of windows of varying optical density increases the efficiency of the electrode encoding scheme — allowing more electrode types or the use of fewer windows.

Using a simple "on/off" embodiment with two "windows" as an example, electrodes intended for use on an infant patient could be identified by having one of the windows transmissive and the other opaque, electrodes for pediatric use could have one window transmissive and the other opaque (opposite of the case for the infant patient), and electrodes for adult use would have both windows opaque. The situation where light is received by both photodetectors could be reserved for self test of the system when no electrode connector is inserted. Thus, if neither of the two photodetectors receives light, the defibrillator identifies the electrodes as being those for use on an adult and follows the adult therapy protocol and energy delivery behavior. While this particular embodiment utilizes the transmissive qualities of light, it can be appreciated by those skilled in the art that other techniques to modify the characteristics of light such as reflection, polarization, absorption, refraction, or diffraction can be used successfully as well.

In yet another embodiment, electromechanical encoding may be provided. In that case interface electronics within the defibrillator such as switches or other means to make or break electrical contact would be activated by mechanical protrusions or depressions in the electrode connector body. Persons skilled in the art can envision several encoding schemes ranging from simple binary (switch open/closed) forms to mechanical barcode equivalents consisting of complex open and closing sequences as the connector is inserted into the electrode connector receptacle. Furthermore, it can be appreciated that switch actuation may be due to other forces such as magnetic or proximity.

In yet another embodiment, electrical contact encoding may be provided. In that case, interface electronics in the defibrillator sense the presence or absence of direct electrical connections between various contacts in the connector socket engaged by mating contacts in a particular connector. The interface electronics could comprise digital electronic inputs resistively pulled up to a power supply, with the connector contacts arranged to pull down the inputs thereby facilitating sensing by a circuit such as a logic element or a comparator. A plurality of contacts could be used in various combinations to indicate one from among a set of possible combinations. For example, with three possible connections to a fourth common connection, the presence of all three connections identifies the electrodes as being those for use on an adult and follows the adult therapy protocol and energy delivery behavior. The connection set could be further extended to implement error detection and/or correction if needed to mitigate hazards that might exist.

In yet another embodiment, RF encoding may be provided. In that case, an RF transmitter and RF receiver are provided in the defibrillator in the vicinity of the connector socket. The connector of this embodiment would have specific resonant electrical characteristics determined by indwelling inductive and capacitive circuit elements that identify the electrode type. The resonant properties of the connector modify the RF signal sent from the RF transmitter to the RF receiver in such a way as to change its amplitude at the receiver as a function of frequency. For example, electrodes intended for use on an infant patient could be identified as having the received signal amplitude at a maximum at 100kHz, pediatric electrodes at 200kHz, and adult electrodes at 400kHz. Thus, for example when a peak frequency of 400kHz is detected, the defibrillator identifies the electrodes as being those for use on an adult and follows the adult therapy protocol and energy delivery behavior.

In yet another embodiment, resistance encoding may be provided. In that case, a connector with specific resistance across sense connections is provided. The defibrillator forms a voltage divider from a reference voltage between a reference resistance and the variable connector resistance and measures the divided voltage with an A/D converter to determine the type of connector installed. For example,

electrodes intended for use on an infant patient could be identified as 1000 Ohms, pediatric electrodes as 2000 Ohms, and adult electrodes as 3000 Ohms. The defibrillator could use a 10000 Ohm reference resistance, in which case an A/D converter reading corresponding to 23% of the reference voltage would indicate the presence of adult electrodes. The defibrillator would then follow adult therapy protocol and energy delivery behavior.

In yet another embodiment, capacitance encoding may be provided. In that case, a connector with specific capacitance across sense connections is provided. The defibrillator may apply a reference voltage to the connector capacitor, and then discharge the connector capacitor into a reference resistance, sensing with a comparator when the voltage has decayed to 37% of the reference. Measuring this decay time with a timer could then be used to determine the type of connector installed. For example, electrodes intended for use on an infant patient could be identified as 0.1 μF, pediatric electrodes as 0.2 μF, and adult electrodes as 0.3 μF. The defibrillator could use a 10000 Ohm reference resistance, in which case a decay time of 3 ms would indicate the presence of adult electrodes. The defibrillator would then follow adult therapy protocol and energy delivery behavior.

In yet another embodiment, magnetic encoding may be provided. In that case, a connector containing one or more magnets with a specific magnetic field may be provided. Based on the strength of the magnetic field, the controller ***12*** adjusts its operation to correspond to the identification. For example, electrodes intended for use on an infant patient could be identified as containing 2 magnets, pediatric electrodes contain 1 magnet, and adult electrodes none. Thus, for example when the detected magnetic field falls below the minimum threshold, the defibrillator identifies the electrodes as being those for use on an adult and follows the adult protocol and energy delivery behavior. As will be appreciated by those skilled in the art, the encoding scheme could employ the orientation of the field or the physical location within the electrode connector body of the detected field.

Further, it will be appreciated by those in skill of the art, that other adjustments to operational behavior could be followed without departing from the scope of the invention.

Turning to **FIG. 2a**, electrode system ***36*** comprises an electrode connector housing ***40*** for connecting the electrode system ***36*** to device (not shown). In this embodiment, the housing ***40*** comprises a cable connector ***50***. The cable connector ***50*** has one or more electrical conductors electrically connected to corresponding sockets within a shell. A pair of electrodes ***42*** ~~is~~ are connected to the housing ***40*** via wires ***44.*** For purposes of illustration, **FIG. 2a** has been depicted showing two electrodes. However, it will be appreciated by those of skill in the art that a plurality of electrodes can be used. For example, from 2-12 electrodes are appropriate for use in monitoring patient ECG. Additional information on electrode connector construction can be found in U.S. Patent No. 5,967,817 by Greenstein entitled "Medical Connector Apparatus," the disclosure of which is incorporated herein.

Turning now to **FIG.2b**, the housing ***40*** of the electrode connector receptacle shown in **FIG. 2a** has been modified so that in addition to providing a cable connector ***50***, it also is adapted to receive a mating cable connector on one end. Thus, one end forms an interior chamber ***52*** for receiving a mating cable connector. Electrical conductors electrically connected to sockets within a shell are located within the interior chamber ***52*** such then when a mating cable connector is inserted into the interior chamber of the receptacle it makes electrical contact between the mating cable connector and housing ***40***. In this embodiment, the receptacle is configured so that it is removable from the electrode pads and the defibrillator and thus is reusable.

FIG. 2c illustrates the adapter set-up shown in **FIG. 2b** with the interior portions outlined. As illustrated, the interior female chamber ***52*** houses two connectors with female chambers. The connectors are adapted to slide over male conductors in a corresponding electrode adapter. The male cable connector end ***52*** has two female chambers each of which contains a male conductor. When the male cable connector end ***52*** is inserted into a corresponding female chamber (for example, in a defibrillator

housing), the male cable connector slides into the female connector, while the two connectors with female chambers slide over the male conductors of the male cable connector.

As will be appreciated by those of skill in the art, the form factors shown in **FIGS. 2a-2c** are provided for illustration only. Other form factors may be used without departing from the scope of the invention.

The major components of an AED are shown in **FIG. 3** in block diagram form. Further detailed information about the operation of an AED can be obtained in U.S. Patent 5,836,993, to Cole for "Electrotherapy Device Control System and Method," the specification of which is incorporated herein. As will be appreciated by those of skill in the art, the invention can be used in a variety of AEDs and is not limited to this configuration, which is used for illustration purposes only.

In this illustration, defibrillator control functions are divided among a microprocessor unit (MPU) ***102*** and two custom gate arrays ***104*** and ***106***.

MPU ***102*** performs program steps according to software instructions provided to it from ROM ***114***. MPU ***102*** controls the operation of certain buttons (such as display contrast buttons ***108***) and certain system LED's ***110*** (such as LED's associated with the shock button and the electrode connector). MPU ***102*** also receives system status information as shown by block ***112***.

Gate array ***104*** implements the memory map to system ROM ***114***. System ROM ***114*** is preferably flash ROM, although EPROM or any other electrically erasable and programmable nonvolatile memory could be used. Gate array ***104*** also controls a display ***118***, a speaker ***120***, and a microphone ***122***. Gate array ***104*** can actuate a relay within the shock delivery and ECG front-end system ***124*** in response to actuation of a shock button ***126*** by a user during treatment mode.

Gate array ***106*** provides a system monitor function by performing automatic self-tests of the defibrillator and its components. The gate array ***106*** displays the operational status of the defibrillator on a status display ***128***. Details of suitable self-

tests may be found in U.S. Patent 5,879,374, to Powers, et al. for "External Defibrillator with Automated Self-Testing Prior to Use," the specification of which is incorporated herein by reference. Gate array ***106*** is also the defibrillator's interface with a user-activated on/off switch ***130***. Gate array ***106*** controls the power management subsystem ***132*** to provide power to operate system components from power supply ***134*** and to provide energy to the shock delivery system's capacitor(s) for a therapeutic shock during treatment mode. Gate array ***106*** also interfaces with the defibrillator's ECG front end, enables the shock delivery system to deliver a shock in response to detection of a patient ECG pattern requiring treatment (and actuation of the shock button), and controls delivery of the shock to electrode connector ***136*** in response to shock delivery status information obtained during delivery of the shock. Further information regarding this last function may be found in U.S. Patents 5,735,879 to Gliner et al. for "Electrotherapy Method for External Defibrillators," and 5,607,454, to Cameron et al. for "Electrotherapy Method and Apparatus," the specifications of which are incorporated herein.

As described previously, electrical connector ***136*** may communicate directly with MPU ***102*** to identify the electrode type, or electrical connector ***136*** may communicate with MPU ***102*** via an identifier receiver that interfaces between the MPU ***102*** and the identifier of the electrical connector ***136.*** For example, in the optical encoding solution, the photodetectors could act as an identifier receiver in communication between the MPU ***102*** and the electrical connector ***136.***

These defibrillator components communicate with each other over suitable communication buses, as shown.

External defibrillator ***100*** can be operated in different modes, such as self-test mode, stand-by mode, set-up mode, patient treatment mode, training mode and code-transfer mode. The operational characteristics of defibrillator ***100*** differ in each mode. In addition, the operational characteristics of the defibrillator in any one of the modes can be changed as explained below.

As is known in the art, while in patient treatment mode, the defibrillator ***100*** typically (1) determines whether electrodes ***137*** are attached to electrode connector ***136***; (2) receives ECG information from a patient through such electrodes; (3) analyzes the ECG information to determine whether a therapeutic shock is advised; and (4) delivers a shock to the patient through the electrodes ***137*** if a shock is advised and if the shock button ***126*** is actuated by a user.

Turning to **FIG. 4**, the method of deploying the invention is shown. Initially, the first responder defibrillator is powered up ***200***. Typically, but not necessarily, after powering the defibrillator, electrode pads are attached to the patient ***202*** and the electrode pads are connected to the defibrillator. The defibrillator then obtains value information from the attached electrode connector via its connector identification system ***204***. The defibrillator then determines the information communicated for the identification from the adapter ***206***. As discussed above, appropriate identification values include, for example: presence or absence of light, when the optical encoding scheme is employed; the state of electrical switches or contacts (open/short) when the electromechanical scheme is employed; resonant frequency characteristics when the RF encoding scheme is employed; resistance when the resistance encoding scheme is employed; capacitance, when the capacitance encoding scheme is employed; gauss, when the magnetic encoding scheme is employed; or any combination thereof.

If the value communicated corresponds to the value assigned for an infant patient ***208***, then the defibrillator follows a therapy protocol that is appropriate for an infant ***218***. If the value communicated corresponds to the value assigned for a child under the age of 8 ***210***, then the defibrillator follows a therapy protocol that is appropriate for a child ***220***. If the value communicated corresponds to the value assigned for an adult patient ***212***, then the defibrillator follows a therapy protocol that is appropriate for an adult ***222***. If the value communicated does not correspond to a recognized value ***214***, or no value is communicated ***214***, then the defibrillator follows a default therapy protocol ***224***. Typically, the default protocol ***224*** is the protocol followed for delivering therapy to an adult patient ***222***.

As discussed above, other modifications falling within the scope of this invention will be apparent to persons of skill in the art. Thus, the invention is not to be limited by the specification, but interpreted according to claims that follow.